National Coalition of Food Importing Associations

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VIA FEDERAL EXPRESS
AND ELECTRONIC MAIL

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: **Docket No. 02N-0278: Comments on Section 307, Prior Notice of Imported Food Shipments Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188)**

Dear Sir or Madam:

President Bush signed Public Law No. 107-188 into law on June 12, 2002. Among other things, the law amends the Federal Food, Drug, and Cosmetic Act ("FDC Act") to better protect the safety and security of the United States food supply. Among these changes, Section 307 of the Public Law imposed new requirements upon the importation of food into the U.S.

The Food and Drug Administration ("FDA") summarizes the new import provisions of Section 307 as follows:

- Amends Section 801 of the FDC Act to require prior notice of imported food shipments. The notice is required to provide the article, the manufacturer and shipper, the grower (if known within the specified time in which notice is required), the country of origin, the country from which the article is shipped, and the anticipated port of entry. If notice is not provided, the article shall be refused admission.

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- Requires the Secretary, after consultation with Secretary of the Treasury, to issue regulations that specify the period of advance notice. The advance notice shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification. The period may not exceed five days.

- Requires the Secretary to promulgate proposed and final regulations by December 12, 2003. If the Secretary fails to meet the deadline, the default period of notice will be no less than 8 hours and no more than five days until the regulation takes effect.

- States that if an article of food is offered for import and prior notice has not been provided, such article shall be held at the port of entry until the importer, owner, or consignee complies. The Secretary, in carrying out this requirement, shall determine whether there is any credible evidence or information indicating that the article presents a threat of serious adverse health consequences or death to humans or animals.

- Amends Section 301 of the FDC Act making it a prohibited act to import or offer for import an article of food in violation of these requirements.

Prior to initiating a complex rulemaking, FDA's Center for Food Safety and Applied Nutrition ("CFSAN") appropriately requested comments from interested parties regarding factors the agency should consider as it proceeds to draft the regulations implementing Public Law No. 107-188. In response, the National Coalition of Food Importing Associations ("NCFIA) is pleased to offer the following comments. The NCFIA is a coalition of trade associations that represent different segments of the United States food importing community. The members of the NCFIA are: American Spice Trade Association; Association of Food Industries; Cheese Importers Association of America; The Cocoa Merchants Association of America Inc.; and the National Fisheries Institute. The five organizations collectively represent over 650 importers and distributors of imported food products nationwide.

Regulations Promulgated "In Consultation with the Secretary of Treasury"

Section 307(a), to be codified at 21 U.S.C. § 381(m)(1) requires that FDA promulgate regulations implementing the requirements of Section 307 "after consultation with the Secretary of Treasury," that is, the U.S. Customs Service ("Customs"). Primary responsibility for administering U.S. laws relating to the import of goods, including food, into the U.S. lies with Customs. FDA is

responsible for determining whether or not an article offered for importation is in compliance with the laws FDA enforces. FDA and Customs have long worked in close cooperation to help assure the lawful importation of foods into the U.S.

Section 307 is essentially overlaying requirements upon an existing system for the notification, inspection, handling, and processing of imported articles, including food. The existing system reflects a considerable body of Customs and FDA laws, regulations, policies, notices, and rulings and has been honed through decades of real world, practical experience. The procedures by which products gain admittance into the U.S. is well known to those in the business, including importers, brokers, consignees, and others. For the most part, the system works well, achieving a proper balance between regulatory oversight and market efficiency.

FDA should follow the letter and spirit of the exhortation to consult with Customs in promulgating rules to implement Section 307; NCFIA urges that FDA not try to "reinvent the wheel." For instance, terms such as "importer," "port of entry," "date of entry," "date of importation," "time of entry," and "shipment" are all defined in Customs regulations. The existing procedures governing the importation of articles, including food, into the U.S. are well-known and well-established in the importing community. FDA should look first to established Customs regulatory definitions and procedures as it promulgates the Section 307 regulations.

Content of Notice

Section 307 requires that importers provide the following in a notice to FDA:

- identity of the article of food being imported or offered for import
- manufacturer of the article
- shipper of the article
- grower of the article if known during the time the notice is required to be provided
- the country from which the article originates
- the country from which the article is shipped
- the anticipated port of entry for the article

This notice is for the purpose of enabling the imported article to be inspected at U.S. ports of entry. Comments upon these notice requirements follow.

New Regulations Should Rely Upon Existing FDA/Customs Notification Procedures

The Section 307 notification requirement is redundant of information gathered through existing procedures. Even before the enactment of Public Law No. 107-188, importers of articles that fall within the jurisdiction of FDA must notify FDA before goods can enter domestic commerce. The notification importers must already make to Customs and FDA includes everything Section 307 would require, except for the identification of the grower, if known.

Each FDA district office receives notification from Customs of all entries of articles under FDA jurisdiction at ports of entry located within the district office's territory. The notification is nearly always accomplished through the Automated Broker Interface ("ABI") system maintained by Customs. It is our understanding that all licensed Customs brokers participate in the ABI and that 96% of all entries are filed through ABI. Through ABI, participating brokers use Custom's Automated Commercial System ("ACS") for cargo release and, for FDA-regulated product, complete an additional screen of information on FDA's own electronic entry system – the Operational and Administrative System for Import Support ("OASIS").

Entries made through the ABI/ACS/OASIS system include all the required Customs entry information, including entry number, entry date, importer identification, port of entry, vessel/voyage information, filer identification, Harmonized Tariff Schedule (HTS) code(s) for the product described in the importing documents (tariff code), information on the foreign shipper, country of origin, quantity of the articles, and value.

For FDA-regulated products, after the broker completes the Customs information, an additional screen of information appears and the broker (or other filer) makes an electronic filing in FDA's OASIS system. In addition to what is already provided on the ACS screen, the filer provides on the OASIS screen for FDA: (1) the seven character FDA Product Code; (2) the Manufacturer's Identification ("MID") code of the foreign manufacturer[1] (3) the MID information of the foreign shipper, including city and country, which may or may not be the same as the foreign manufacturer; (4) the country of origin.

Thus, the ABI/ACS/OASIS system captures all of the information Section 307 requires, save the identity of the grower, if known, and a substantial amount of additional information as well. The grower identity information could easily be provided as an additional line on the OASIS screen.

[1] Customs assigns an MID code for each foreign firm. This code is subsequently transmitted to FDA's OASIS screen as the uncoded name of the identified firm.

Identity of article of food

Section 307 requires notification in the case of "an article of food that is being imported or offered for import into the United States." Section 307 and Public Law No. 107-188 do not define "article" or "food" but Section 307 is codified within the FDC Act. The FDC Act defines food as:

> (1) articles used for food or drink for man or other animals; (2) chewing gum, and (3) articles used for components of any such article.

21 U.S.C. § 321(f).

It would have been preferable if Congress had expressly incorporated the FDC Act's existing definition of "food" within Section 307. However, there is no indication that Congress intended to include within Section 307, anything other than the foods, and articles within foods, already defined in 21 U.S.C. § 321(f). Indeed, Section 307 states that it applies to "an article of food," which may reasonably be interpreted to encompass "articles used for food or drink" (§ 321(g)(1)) and the "articles used for components of any such article [used for food or drink]" (§ 321(g)(3)).

The most common sense reading of Section 307 is that an "article of food" is that which is already deemed to be food under the FDC Act, no more, and no less.

Identity of the manufacturer and shipper

OASIS already captures the identity of the foreign manufacturer and shipper of the imported article. The importer enters the MID codes for both entities into the ABI/ACS/OASIS screens and the interface transmits the uncoded name of the firms to FDA. These identifications should satisfy the requirements of Section 307.

Identity of the grower

Section 307 requires that the importer include in the notice to FDA:

> if known within the specified period of time that notice is required to be provided[2], the grower of the article

[2] The period in which notice is required is discussed further below.

This language is plain. If the identity of the grower of the imported food article is known, it must be disclosed. If not known, it need not be disclosed. There is no basis, in the plain language of the statute or in its legislative history that justifies imposing a further obligation of inquiry to investigate who the grower of an article is. Any rule FDA proposes should reflect Congress' unambiguously stated intent.

Identification of originating country

Section 307 requires identification of "the country from which the article originates." The ACS and OASIS systems both capture the imported article's country of origin. The country of origin identified in the ACS/OASIS system should satisfy this requirement.

Identification of country from which article is shipped

The ABI/ACS/OASIS interface includes identification of the country from which the article was shipped. This information should satisfy shipping country identification as required by Section 307.

Anticipated Port of Entry

The term "port of entry" is defined within Customs regulations (19 C.F.R. § 101.1) and should apply here. The port of entry is provided on the Customs ACS screen and is forwarded to FDA as part of OASIS. This information should satisfy the Section 307 requirements.

Other Aspects of the Notice

Currently, the customs broker completing the information screens within the ABI/ACS/OASIS system assigns a Customs entry number to the merchandise. For ease of tracking the food articles, NCFIA recommends that FDA track the imports using the Customs entry number. The Customs entry number is available to FDA through the OASIS system.

The electronic notification system should provide for an automatic reply from FDA. In this way, the submitting broker will immediately receive confirmation that the imported food articles are in compliance with the Section 307 notice requirements.

Timing of Notice

Section 307 states:

> notice [shall be] provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days.

As a general matter, NCFIA urges FDA to be very flexible in its notice requirements. The existing ABI/ACS/OASIS system of interface and notification has worked well. FDA personnel have a long history of reviewing these electronic submissions contemporaneous to an article's arrival into U.S. ports. FDA is able to determine at the time of submission of Customs documentation which imported articles should be sampled and inspected, and which should be given a "May Proceed." The current system has provided for adequate oversight over imported goods without unnecessarily disrupting the orderly movement of goods in commerce. NCFIA believes any new regulations implementing Section 307 should respect these current practices and customs.

In the spirit of flexibility and consistency, NCFIA urges FDA to look to the upper limits for notification prior to importation as provided in Section 307 and that Customs has adopted. Section 307 prohibits FDA from requiring that an importer give more than five days notice prior to importation. Similarly, Customs permits filing of entries up to five days prior to the estimated arrival date of the merchandise. FDA surely has no objection to a similar maximum notice of five days.

The issue of minimum notice is more difficult. The statute says FDA may not require prior notification in excess of five days. The import community wishes to aid FDA in its mission of keeping the U.S. food supply safe, pure, and abundant. In the view of industry, however, the current ABI/ACS/OASIS notification system is working well. Upon receipt of the electronic notification, FDA can issue a Notice of Sampling, and halt the further movement of an imported article until the agency can review the imported article more closely. Any tinkering with the current system may create delay and expense, without necessarily enhancing oversight of imported goods. NCFIA urges FDA to look most closely at how the existing system already accommodates requirements of Public Law No. 107-188.

Flexibility in setting minimum notice requirements is necessary because the amount of notice that is feasible to provide depends upon the type of goods (quota versus non-quota class

merchandise) and the mode of transport (truck, air, maritime). A single period of minimum notice may be reasonable in some instances, but impossible in other situations. The timeframes for notice discussed below reflect the current commercial realities and practices of the importing business.

Air freight

Generally, for merchandise traveling by air, Customs dictates that the ABI/ACS electronic submission of information must be made on a "wheels up" basis. That is, the broker or other filer may not submit the entry into the ACS system until the shipping plane's wheels are up at the point of departure. While most international flights into U.S. ports of entry are longer than four hours in duration, this is not true of many international flights originating in Canada, Mexico and the Caribbean.

NCFIA requests that FDA follow the Customs "wheels up" rule as to merchandise traveling by air in establishing a minimum notice requirement. An importer should notify FDA of the shipment during the period commencing with the time the plane leaves the ground at the point of departure and ending with the expiration on the date of importation (as defined in 19 C.F.R. § 101.1). This is consistent with current practices of filing Customs entry documents for air freight and provides FDA sufficient notice to make decisions regarding admissibility of merchandise.

Ocean Cargo

Several unusual factors need to be considered when establishing a minimum notification period for ocean-going vessels. These are discussed below.

Ocean voyages are longer, and, therefore, could potentially accommodate a longer notice period. However, ocean voyages are also potentially subject to great variability and changes in arrival schedules. Weather, mechanical failures, and similar problems can significantly delay trans-ocean shipments. The five-day maximum for filing entries with Customs is measured from the estimated time of arrival ("ETA") into port the steamship company provides to the piers where the boat will dock. This information, in turn, is reported to Customs and Customs brokers. If the vessel's arrival is delayed, then the steamship company modifies the reported ETA and the importer modifies its entry to the ACS system. Consequently, any maximum prior notice needs to be sufficiently flexible to allow for these types of changes in ETA.

Also, while some ocean journeys are very long, significant traffic into U.S. ports originates from the Caribbean. Journeys from these ports could be as short as twelve hours. For such shipments, brokers typically do not have all the documentation necessary to make the ACS/OASIS entry until a few hours prior to the vessel entering the U.S. port of entry.

For these reasons, the NCFIA urges FDA to adopt a minimum notice requirement of four hours prior to estimated time of importation for non-quota class maritime cargo. The complex issues raised by quota class goods is discussed below.

Many FDA-regulated imported foods are subject to a tariff-rate quotas, such as dairy products, peanuts, sugar, and sugar-containing products. Such quota merchandise is subject to Customs "live entry" requirements under 19 C.F.R. § 132.11a. Under these regulations, the importer may not file entry documents into the ABI/ACS until the "date of importation" -- the date on which the vessel actually arrives within the limits of a port in the United States with intent then and there to unlade such merchandise. 19 U.S.C. § 101.1. Thus, if the Section 307 notification to FDA is to occur concurrently with the ABI/ACS/OASIS submission, the notification for food subject to quotas cannot be made until after the vessel arrives within the port's limits. Practically speaking, it will be at least four hours, and likely much longer, from the time the vessel enters the port's limits, until the time the vessel actually docks and is able to begin unloading.

NCFIA recommends, therefore, that the Section 307 minimum notification period for foods subject to quotas follow Customs' requirements for live entries. The Section 307 minimum notification should be made concurrently with the filing of the entry documents, after the time the vessel enters the port's limits and before the vessel is unloaded.

Cargo by Truck

Currently, it is common business practice in the case of products entering the U.S. from Canada and Mexico for the driver to present the Customs entry forms at the border crossing/port of entry. In short, there is generally no advance notice of the shipment through the ABI/ACS/OASIS system.

It will be a severe burden upon commerce if shippers are forced to abandon this system. Advance notice is especially unworkable for highly perishable items, such as fresh fish and seafood and fresh fruits and vegetables entering the U.S. from Canada and Mexico. Furthermore, a significant percentage of truck traffic from Canada and Mexico into the U.S. involves short journeys, and are often less than four hours.

NCFIA urges FDA to continue this practice and permit importers to comply with Section 307 notification requirements by presentation of the notice at the border simultaneously with the requisite Customs entry documentation. If, however, FDA demands prior notice of truck shipments from Canada and Mexico, than the agency should consider the following factors:

- Under the Customs-Trade Partnership Against Terrorism (C-TPAT), shipments from participating importers are entitled to expedited processing at the border. Customs designates participating importers as "low risk status," if they have a demonstrated a history of regulatory compliance and supply chain integrity. FDA should adopt these determinations and permit a shorter notification window for importers Customs has designated as low risk status.

- FDA should permit a shortened notification window for any shipments of highly perishable goods, such as fresh fish and seafood, and fresh produce.

- FDA should permit a shortened notification window for routine truck shipments that are repetitive and regularly scheduled.

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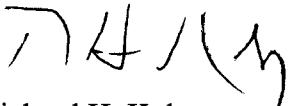
NCFIA thanks FDA for the opportunity to submit these comments. The food importing community is ready to assist the agency in implementing the many complex requirements of Public Law No. 107-188 to help ensure that the U.S. food supply remains safe, pure, and abundant.

Very truly yours,

National Coalition of Food Importing Associations



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